



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,499	01/12/2004	Bernhard Freund	0652.1760006	8272
26111	7590	09/17/2007		
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER TREYGER, ILYA Y	
			ART UNIT 3709	PAPER NUMBER
			MAIL DATE 09/17/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/754,499

Applicant(s)

FREUND ET AL.

Examiner

Ilya Y. Treyger

Art Unit

3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 19-24 is/are rejected.
- 7) ☒ Claim(s) 14-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 06/30/2005; 08/20/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

Claims 1-24 of US Application 10/754,499, filed 01/12/2004, are presented for examination.

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claim 1 of U.S. Patent No. 6,685,691. For double patenting to exist as between the rejected claims and patent claim 1, it must be determined that the rejected

Art Unit: 3709

claims are not patentably distinct from claim 1. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claim 1 and, if so, whether those differences render the claims patentably distinct.

3. Claim 1 of parent recites “a foil bag being closed at both its ends and which is collapsible at a differential pressure below 300 hPa (300 mbar) and having a welded seam for closing a first end of said foil bag, wherein said welded seam extends substantially transversely with respect to a longitudinal axis of said foil bag and at least a portion of said welded seam extends partially in the longitudinal direction of said foil bag, and wherein said foil bag plastically and irreversibly collapses in a predetermined manner such that said foil bag retains its initial length after emptying”, “a flange for closing a second end of said foil bag, wherein said flange is sealingly disposed on said second end of said foil bag, said flange including a guide passage formed in said flange”, “a sealing location disposed within said guide passage for sealingly fitting said container onto said discharge connection member”, and ” a pierceable membrane to seal said container whereby said pierceable membrane is pierced said discharge connection member when said container is fitted onto said discharge connection member; and an inhalable medicament preparation disposed in said container, that is deliverable in a dosage of 10  $\mu$ l to 50  $\mu$ l”.

4. It is clear that all the elements of claim 1 are to be found in claim 1 of the parent. The difference between claim 1 of the application and claim 1 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 1 of the patent is in effect a “species” of the “generic” invention of claim 1. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29

Art Unit: 3709

USPQ2d 2010 (Fed. Cir. 1993). Since claim 1 is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1.

5. Claim 2 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,685,691 in view of Savitt et al. (US 5,297,537).

Art Unit: 3709

Freund discloses a container for a medicament for use as an interchangeable cartridge in an inhaler, the container being gas-tight and liquid-tight, comprising:

a sealed-edge foil bag which is collapsible at a differential pressure below 300 hPa (300 mbar), wherein said foil bag plastically and irreversibly collapses in a predetermined manner such that said foil bag retains its initial length after emptying, said foil bag having at least one welded seam to seal the edges of said foil bag and close a first end of said foil bag;

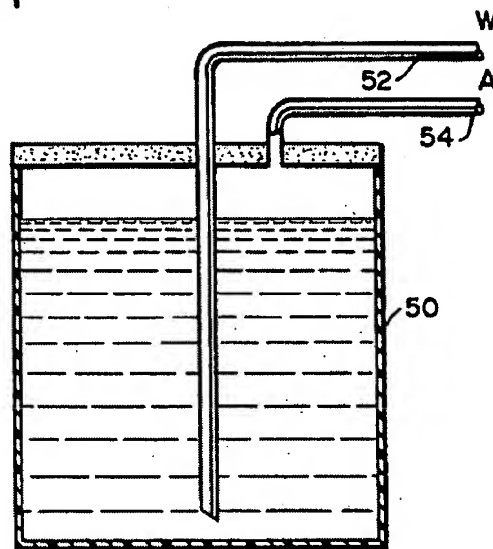
a one-piece flange sealingly connected to a second end of said foil bag for closing said second end of said foil bag, said flange having a guide passage formed therein for sealingly fitting said container onto a discharge connection member of the inhaler; and

a pierceable membrane to seal said container whereby said pierceable membrane is pierced by the discharge connection member when said container is fitted onto the discharge connection member (See Claim 1).

6. Freund does not expressly disclose the container, wherein said at least one welded seam is of a T-shaped configuration.

7. Savitt teaches that it is known to use container of the T-shaped configuration (See Fig. 4).

**FIG.4**



8. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the container of Freund with the T-shape configuration, as taught by Savitt because such modification would improve the consumer preferences of the product.

Art Unit: 3709

Claim 3 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,685,691 in view of A. Schweikert (US 3,445,982).

Freund discloses a container for a medicament for use as an interchangeable cartridge in an inhaler, the container being gas-tight and liquid-tight, comprising:

a sealed-edge foil bag which is collapsible at a differential pressure below 300 hPa (300 mbar), wherein said foil bag plastically and irreversibly collapses in a predetermined manner such that said foil bag retains its initial length after emptying, said foil bag having at least one welded seam to seal the edges of said foil bag and close a first end of said foil bag;

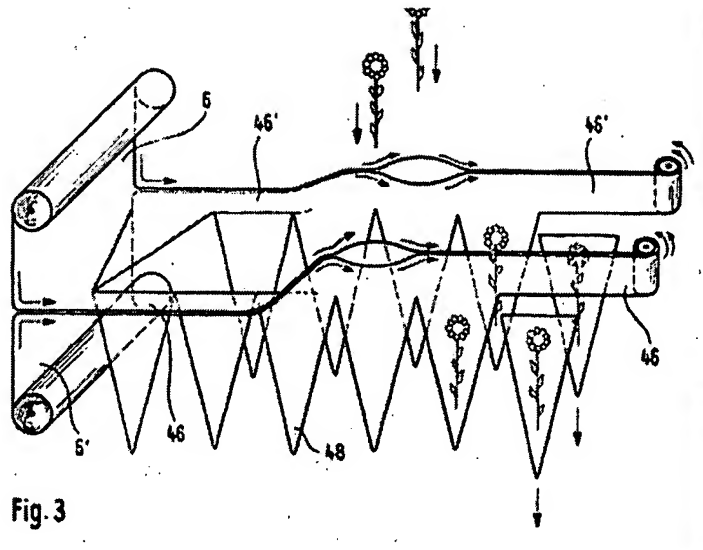
a one-piece flange sealingly connected to a second end of said foil bag for closing said second end of said foil bag, said flange having a guide passage formed therein for sealingly fitting said container onto a discharge connection member of the inhaler; and

a pierceable membrane to seal said container whereby said pierceable membrane is pierced by the discharge connection member when said container is fitted onto the discharge connection member (See Claim 1).

9. Freund does not expressly disclose the container, wherein said at least one welded seam is of a V-shaped configuration.

10. Schweikert teaches that it is known to use container of the V-shaped configuration (See Fig. 3).





11. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the container of Freund with the V-shape configuration, as taught by Schweikert because such modification would improve the consumer preferences of the product.

12. The rest of claims 4-13 are anticipated by claims 14-19, and 23-25 of U.S. Patent No. 6,685,691.

13. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claim 23 of U.S. Patent No. 6,685,691. For double patenting to exist as between the rejected claims and patent claim 23, it must be determined that the rejected claims are not patentably distinct from claim 23. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claim 23 and, if so, whether those differences render the claims patentably distinct.

14. Claim 23 of patent recites "a foil bag being closed at both ends and which is collapsible at a differential pressure below 300 hPa (300 mbar), said foil bag having a welded seam for closing a first end of said foil bag wherein said welded seam extends substantially transversely

Art Unit: 3709

with respect to the longitudinal axis of said foil bag and at least a portion of said welded seam extends partially in the longitudinal direction of said foil bag, wherein said foil bag plastically and irreversibly collapses in a predetermined manner such that said foil bag retains its initial length after emptying, and wherein said foil bag is made from a composite material, said composite material comprising an inner foil made of a copolymer, a diffusion-tight central layer, and an outer foil of a plastic material, wherein the melting temperature of said plastic material is higher than the melting temperature of said inner foil”, “a flange for sealingly closing a second end of said foil bag, wherein said foil bag is welded to said flange on a periphery thereof and having a guide passage formed therein, wherein said guide passage includes a press fit and/or a sealing location for sealingly fitting said container onto a discharge connection member of the inhaler, whereby the sealing location is required if the sealing effect of the press fit is not sufficient”, “a pierceable membrane being disposed at an end of or within said guide passage whereby said pierceable membrane is pierced by said discharge connection member when said container is positioned within the inhaler”, and “a casing made of a metal of plastic material, wherein said casing is connected to said flange so that said foil bag is disposed within said casing”.

15. It is clear that all the elements of claim 19 are to be found in claim 23 of the parent. The difference between claim 19 of the application and claim 23 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 23 of the patent is in effect a “species” of the “generic” invention of claim 19. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 29

Art Unit: 3709

USPQ2d 2010 (Fed. Cir. 1993). Since claim 16 is anticipated by claim 23 of the patent, it is not patentably distinct from claim 23.

16. Claim 20 is rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claim 1 of U.S. Patent No. 6,685,691. For double patenting to exist as between the rejected claims and patent claim 1, it must be determined that the rejected claims are not patentably distinct from claim 1. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claim 1 and, if so, whether those differences render the claims patentably distinct.

17. Claim 1 of parent recites “a foil bag being closed at both its ends and which is collapsible at a differential pressure below 300 hPa (300 mbar) and having a welded seam for closing a first end of said foil bag, wherein said welded seam extends substantially transversely with respect to a longitudinal axis of said foil bag and at least a portion of said welded seam extends partially in the longitudinal direction of said foil bag, and wherein said foil bag plastically and irreversibly collapses in a predetermined manner such that said foil bag retains its initial length after emptying”, “a flange for closing a second end of said foil bag, wherein said flange is sealingly disposed on said second end of said foil bag, said flange including a guide passage formed in said flange”, “a sealing location disposed within said guide passage for sealingly fitting said container onto said discharge connection member”, and “a pierceable membrane to seal said container whereby said pierceable membrane is pierced said discharge connection member when said container is fitted onto said discharge connection member; and an inhalable medicament preparation disposed in said container, that is deliverable in a dosage of 10  $\mu$ l to 50  $\mu$ l”.

Art Unit: 3709

18. It is clear that all the elements of claim 20 are to be found in claim 1 of the parent. The difference between claim 20 of the application and claim 1 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 1 of the patent is in effect a "species" of the "generic" invention of claim 1. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 1 is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1.

19. The rest of claims 21-24 are anticipated by claims 1-3 and of U.S. Patent No. 6,685,691.

#### ***Allowable Subject Matter***

20. Claims 14-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4847462 disclose a Method and apparatus for making fluorocarbon film plastic bags using a laser. US 3646723 disclose a SYSTEM FOR FILLING A FLEXIBLE SEALABLE CONTAINER. US 3673765 disclose a PACKAGING DEVICE. US 5297537 disclose a Disposable liquid supply kit for use in an endoscope. US 2952299 disclose a Method and apparatus for making bags of thermoplastic tubing.

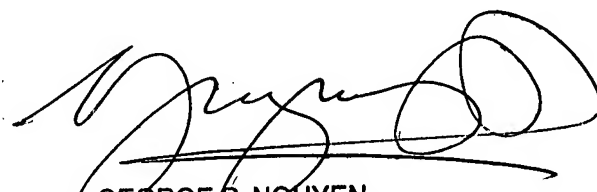
Art Unit: 3709

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ilya Y. Treyger whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Nguyen can be reached on 571-270-1431. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ilya Y. Treyger  
Examiner  
3709



GEORGE B. NGUYEN  
SUPERVISORY PATENT EXAMINER